

Bone conduction hearing kit for children with glue ear

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INTRODUCTION

Background

Hearing loss is one of the most common disabilities in childhood.¹ One in 10 children starting school in UK or Europe have hearing loss secondary to glue ear (Otitis Media with Effusion (OME)).^{1,2} This is much higher in lower income countries. Eighty per cent of children have at least one episode of glue ear, where fluid builds up behind their eardrum after a cough, cold or ear infection. OME often self-resolves or children can be offered grommets (also known as 'tympanostomy tubes') if persistent.³

Grommets 'only offer short term hearing improvement'⁴ of ~12 dB, diminishing to ~4 dB 6–9 months later,⁴ therefore grommets improve a child's symptoms for about 6 months while 'natural resolution continues'.³ Grommet insertion is common, requiring a general anaesthetic, and risks include opening the middle ear to infection (requiring treatment in approximately a third of patients), perforation (1% of cases) and variable scarring the eardrum (tympanosclerosis).

Hearing aids are not an easy solution, since glue ear fluctuates and multiple audiology appointments are needed to avoid overamplification or underamplification.

Children need to hear to learn. Poor hearing can affect speech, language, social skills, listening, attention and learning. While some children catch up learning after an episode of glue ear, others do not. Glue ear mostly affects those under 8 years old, which is a critical time for development, speech acquisition, learning, writing, spelling and phonics.⁵ Deafness at this time interferes with speech development, language, communication, auditory processing, self-esteem, socialisation, listening and learning.⁵

Summary box

What are the new findings?

- Cheap alternatives to hearing aids can be used for children with glue ear.
- Care for glue ear can be delivered remotely.
- The kit (Bone conduction (BC) headphones, microphone and Hear Glue Ear app) is acceptable to children and their families.

How might it impact on healthcare in the future?

- Further clinical trials could evidence cost-effectiveness and clinical effectiveness of the solution.
- Grommets may be able to be avoided in many cases of glue ear.
- Mild, fluctuating cases of glue ear could be offered early hearing support.
- Schools may need further sensory support training to assist children in the classroom situation.

Operational aims and objectives

Bone conduction hearing aids work well in OME because they send sound as a vibration through the bones of the skull directly to the cochlea (by-passing the eardrum and middle ear bones where the fluid, mucus or 'glue' accumulates) but they are often prohibitively expensive, costing up to £3000. Bone conduction headphones are marketed at cyclists, allowing sound from mobile phones to be directed straight to the cochlea while sound from traffic noises still accessible through the ear canals. These headphones cost ~£100 commercially (figure 1). An initial study in 2016–2018 trialled these simple bone conduction headphones paired to a microphone for the first time in children with OME.⁶

The Hear Glue Ear app was trialled in 2019.⁷ It was codesigned with a patient



Figure 1 A child trying a headset paired to a microphone (the microphone is usually clipped to the parent or teacher's clothing).

and public voice group. Parents wanted to support their children over the watchful waiting period, prevent their child from falling behind and wanted trusted information about other aspects of glue ear (tinnitus, auditory processing difficulties, speech and language, education, balance, etc). They also needed a way to estimate their children's hearing at home, as well as speech and language enrichment for their child. The app was CE ('Conformité Européenne': Conforms to European safety and health requirements) marked as a class 1 medical device, awarded an ORCHA (Organisation for the Review of Care and Health Apps) approval badge and won several awards. The Raspberry Pi Trading Limited has a product set (Bone Conduction (BC) headset and microphone kit) to be widely available at the end of 2021 for ~£55. The Hear Glue Ear app (figure 2) is currently free and on Apple and Android app stores.

A trial was conceived to test whether sending BC headphones, microphone (the kit) and details of the free Hear Glue Ear app to families for self-management with remote support would be an acceptable way to manage OME. Online supplemental appendix 1 shows the instructions sent to parents.

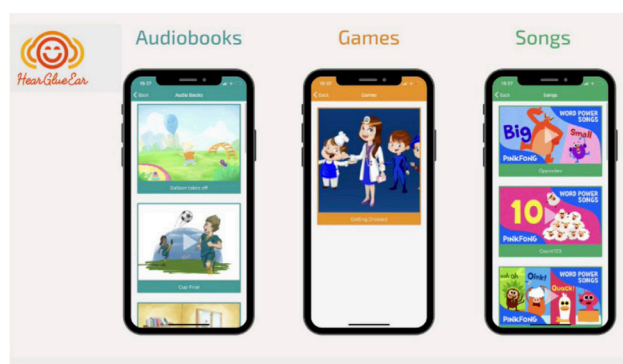


Figure 2 The Hear Glue Ear app.

METHODS

During the first wave of the 2020 COVID-19 pandemic in the UK children's audiology services and grommet operations were completely stopped. Children diagnosed with OME (hearing worse than 25 dB at two or more frequencies in at least one ear) and those on a grommet operation list were invited to enrol in a single arm, a prospective study assessing the use of bone conduction headset, wireless Bluetooth microphone 'the kit' and Hear Glue Ear app from July 2020. It was not possible to recruit a control group while there was no standard of care during the pandemic.

Participants were posted the kit for use at home and school with instructions for the headset and details of the Hear Glue Ear app. The parents were told to follow instructions and asked to self-check the headset volume (if the parent had normal hearing) to a comfortable level before handing it to their child.

Within the first 3 weeks, parents answered questions about their child's hearing by completing a standardised OMQ-14 questionnaire (Otitis Media Quality of life questionnaire to assess impact of ear problems in children)⁸ with and without the kit. Follow-up consultations were remote, by video or telephone over 3 months. A website (www.hearglueear.wordpress.com), initially made solely for research participants, communicated study details, results and publications.

RESULTS

Study population

Twenty-six children between 3 and 11 years (average age 5 years) were enrolled, which was 82% of children on the local grommet (tympanostomy tubes) operation list. Before lockdown in March 2020, the average (mean) hearing loss in the group was a mild hearing loss at frequencies of 0.5, 1, 2 and 4 kHz ranging from 0 to 65 dB.

Kit set-up

Twenty families started using the kit successfully before a consultation with a researcher whereas the remaining six had waited for a call first. All paired the device using written instructions with seven (28%) using the additional video instructions provided. Following the initial set-up, four families required additional help to use the kit later in the study.

Parent's reported perception of their child's hearing

In the 3 months before the kit was supplied, 19 out of 26 parents reported their child's hearing as poor or very poor. One parent was unsure. With the kit in use, no parents reported hearing as poor or very poor and 24 out of 26 reported it as 'normal' or 'slightly below normal' (figure 3). Two parents were unsure.

Twenty-three out of 26 parents reported that the child 'often' or 'always' had difficulty hearing in a group before the intervention, compared with 22 out

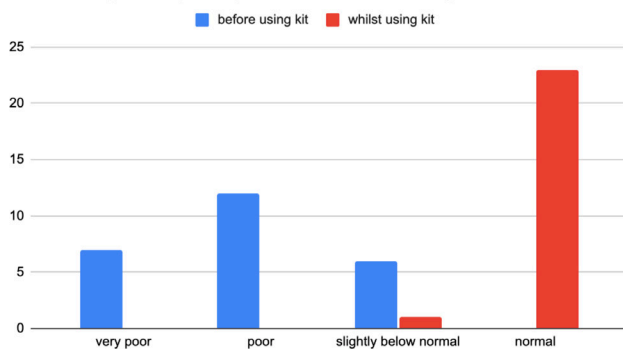


Figure 3 Parents' reported perception of child's hearing.

of 26 saying their child rarely or never had problems hearing in a group when using the kit.

Other results

Usage of kit

Families tailored their use of the kit depending on the personalised needs of their child. Some found headset paired to the microphone was the most valuable, others used the headset paired to computers/iPads. Sixty-six per cent (17) used the Hear Glue Ear app at home, 8% (2) on car journeys and 26% (7) did not use it at all. Some preferred to use the headset paired with a tablet for Zoom calls with family, health professionals, music teachers, school/online lessons or audio books and films.

All the children looked after the kit. No one lost or broke the headsets. Two parents reported their children were 'very protective over their headphones'. Three families reported their child 'had worked out how to pair it with everything in the house'. Further comments can be seen in online supplemental appendix 2.

Usage of kit at schools

Fifty-eight per cent (15) took the kit to school or nursery. One wanted to take the kit to school but parents advised against it. One teacher said she 'would see' if the child needed it in class so the child continued to use it at home.

One family who could use the kit at home found the teacher struggled to pair it at school. Families used the teacher information sheet when taking the kit to school. One family commented that the school took their child's hearing more seriously as a result of the need for the headset: one parent commented the headset was a visual cue to others their child needed support. Three parents mentioned schools needed more support, or more resources, to use the kit at school.

Three parents contacted their school's special educational needs coordinator and two teachers addressed the class about the headsets: this helped children use the kit seamlessly at school and helped discuss their hearing with their peers: one child checked daily that

the kit had been charged overnight and placed the kit back in his school bag.

Outcomes at end of study

At the end of the study, families were able to keep the kit and contact the team if they had questions or concerns in line with ethical approval. All families chose to keep the kit at the end of the study, even if the child's hearing improved, often fearing glue ear may return with the child's next cough, cold or ear infection, as 'lockdown' was lifted. No child had a grommet operation by December 2020 (9 months after lockdown). Three families said they would continue to use the kit rather than have a grommet operation. Three children's glue ear fully resolved while they were using the kit. The majority of families found the remote management strategy acceptable and thought their child had benefited.

DISCUSSION

Remote management of glue ear in this way has many advantages: improving children's hearing at an important stage of their development; preventing sequelae of hearing loss; preserving face-to-face hospital appointments with surgeons and audiologists for those needing them most; reducing travel to clinics with small children; empowering the parents/carers to support their children; enabling children to hear online learning more clearly; enabling children to hear when face masks obscured lip reading; cost savings for the National Health Service (NHS) from cost-effective hearing support and reduction in the number of grommet operations.

Importantly, the parents' comments showed their children benefited from the kit, helping them hear better at home and school, and in some cases improved their pronunciation, behaviour and listening anxiety.

One family who could use the kit at home found the teacher struggled to pair it at school. The wide variation in support and acceptability in use of the kit at school suggests that the teacher's instructions need to be more comprehensive and teacher-of-the-deaf (TOD) support may be needed in this setting.

Limitations of the study included that it was short term, non-randomised and could only recruit a small number of children.

CONCLUSIONS

Innovative use of bone conduction headphones, a microphone and the Hear Glue Ear app, sent through the post to patients, is a novel, new and effective approach to the management of glue ear and its resulting hearing loss, especially when families have reduced access to audiology or Ear Nose and Throat (ENT) services such as during the COVID-19 pandemic. The hearing screen on the Hear Glue Ear app allows families to monitor their child's hearing at home and use the kit as needed. Fewer grommet insertions were required by

the end of the study. Families found this was an acceptable and positive management strategy.

Further research should be targeted at the scaling of this intervention—detailed economic analysis including the cost of grommets and clinic visits, randomised trials to compare with standard treatment and rigorous qualitative analysis of the key issues and themes for children, families, their parents and teachers.

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Collaborators Expert Otolaryngology and Audiology Collaborators: Josephine Marriage, Roger Gray.

Contributors TMHB: conceptualisation, data curation, seeking donation of equipment for study, methodology, investigation, visualisation, writing original draft, review and editing, literature search, figures, study design, data collection, data analysis, data interpretation, writing. IFO'C: methodology, recruitment, investigation, manuscript study design, review of drafts and editing. JB: methodology, recruitment, data curation, manuscript study design, data interpretation, helped verify underlying data, review and editing of drafts. CM: conceptualisation, data curation, supervision, verified underlying data, manuscript figures, data analysis, data interpretation, writing, review and extensive editing.

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Competing interests TMHB helped create the free, charity-funded Hear Glue Ear app that was used in this study. TMHB conceptualised the use of the bone conduction headphones and microphone.

Patient consent for publication Parental/guardian consent obtained.

Ethics approval The study was registered IRAS 262816 and approved by the Solihull REC and Health Research Authority (HRA).

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